JUL 11 2002

K021817

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Trade Name:	Aaron 950 High Frequency Electrosurgical Generator
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400)

The **Aaron 950 High Frequency Electrosurgical Generator** is a non-sterile, reusable electrosurgical generator, which is designed to generate high frequencies (RF) of high voltage and low amperage current.

The **Aaron 950 High Frequency Electrosurgical Generator** is intended to be used for all electrosurgical cut, blend, coagulation, fulguration, and bipolar procedures.

The **Aaron 950 High Frequency Electrosurgical Generator** is substantially equivalent to the Aaron Medical **Aaron 1200 High Frequency Electrosurgical Generator (K980366)** in operation, intended use, materials, energy source, output, method of preparation, and performance claims and is substantially equivalent to the **Aaron 900 High Frequency Electrosurgical Dessicator** in terms of remote power selection via handpiece. The **Aaron 950 High Frequency Electrosurgical Generator** incorporates rotary dial or handpiece selected energy output, allowing independent setting of cut and coagulation mode energy. Preset mode and output power button have also been incorporated into the **Aaron 950**.

Testing performed on the **Aaron 950** indicates that the device is substantially equivalent in its performance and method of operation.

Hazard analysis evaluations are performed on the **Aaron 950**. There are no new hazards presented with the use of the **Aaron 950** as compared with the predicate devices.

In conclusion, the **Aaron 950** High Frequency Electrosurgical Generator is substantially equivalent to the predicate devices (Aaron A900 and Aaron A1200) in methods of operation, intended use, and results derived from operation.

Submitted By: Richard Kozloff
Vice-President ; Quality Assurance/Reg. Affairs
Aaron Medical Industries
7100 30th Avenue North
St. Petersburg, FL 33710

Contact Person: Richard Kozloff
Date: May 30, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Mr. Richard Kozloff
Vice President
Quality Assurance
Aaron Medical Industries
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K021817
Trade/Device Name: Aaron A950 High Frequency Electrosurgical Generator
Regulation Number: 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: May 30, 2002
Received: June 3, 2002

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021817

Device Name: Aaron A950 High Frequency Generator; Model A950 and A950-220

Indications for Use:

The Aaron 950 High Frequency Electrosurgical Generator models are intended to be used for all electrosurgical cut, blend, coagulation, fulguration, and bipolar procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021817

(Optional Format 3-10-98)